UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to all cases.	)	

CASE MANAGEMENT ORDER NO. 39
(SUMMARY OF MDL 2740 PROCEEDINGS UPON SUGGESTION OF REMAND OR TRANSFER)

On October 4, 2016, the Judicial Panel on Multidistrict Litigation ("JPML") transferred 28 civil actions to this Court for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407.[1] The JPML concluded that these actions all shared common factual questions, including whether Taxotere (docetaxel), a chemotherapy drug, causes permanent hair loss, whether defendants were aware of this possible side effect, and whether they failed to warn patients.[2] Since that time, more than 15,000 lawsuits have been filed in the MDL, and 10,734 cases are currently pending in this Court.[3]

Plaintiffs in this MDL are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[4] that Plaintiffs were administered for the treatment of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi"). Plaintiffs allege that the drug caused permanent

[1] *See* In re Taxotere (Docetaxel) Prod. Liab. Litig., MDL 2740, 2016 WL 5845996 (U.S. Jud. Pan. Mult. Lit. Oct. 4, 2016).
[2] *Id.*
[3] U.S. JUDICIAL PANEL ON MULTIDISTRICT LITIGATION, MDL STATISTICS REPORT – DISTRIBUTION OF PENDING MDL DOCKETS BY DISTRICT 2 (Feb. 16, 2023), https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-February-16-2023.pdf.
[4] Docetaxel is the generic version of Taxotere, though the Court uses the term "generic" loosely.

chemotherapy induced alopecia ("PCIA"). Plaintiffs assert several claims, including failure to warn, negligence, negligent misrepresentation, fraudulent misrepresentation, and fraudulent concealment.

As the transferee court, the Eastern District of Louisiana maintains on its website a summary of actions taken in this docket.[5] The JPML docket number is MDL-2740, and this Court's docket number is 2:16-md-02740-JTM-MBN. This Order outlines the proceedings that have occurred in the MDL since its 2016 inception and summarizes the Court's pretrial rulings applicable to all MDL cases. The purpose of this Order is to assist trial judges in transferor courts who may preside over the remaining discovery and trial of an individual Taxotere case. A copy of this Order will be provided to the transferor court upon transfer or remand, along with MDL filings relevant to the remanded case.

I. THE MDL PROCEEDINGS

A summary of the MDL proceedings is provided below to assist courts on remand, if ordered by the JPML, and courts receiving transfers under 28 U.S.C. § 1404(a).

A. Master Complaint and Short Form Complaint

Pretrial Order No. 15, entered February 10, 2017, set forth the deadlines for the filing of master and short form complaints, motions to dismiss, and master answers.[6] Plaintiffs filed a Master Complaint on March 31, 2017.[7] Plaintiffs then filed a First Amended Master Complaint to name certain Defendants correctly.[8] Defendants moved to dismiss the Master Complaint, which this Court granted in part. The Court dismissed Plaintiffs' claims for

[5] *See* https://www.laed.uscourts.gov/case-information/mdl-mass-class-action/taxotere.
[6] Rec. Doc. 230 (Pretrial Order "PTO" 15).
[7] Rec. Doc. 312 (Master Long Form Compl. & Demand for Jury Trial).
[8] Rec. Doc. 689 (First Am. Master Long Form Compl. & Demand for Jury Trial).

strict product liability for misrepresentation (Count II) and breach of express warranty (Count VIII) from the First Amended Master Complaint.[9] Plaintiffs then filed a Second Amended Master Complaint on September 27, 2018.[10]

The Second Amended Master Complaint remains the operative pleading. It asserts the following state-law claims: failure to warn (Count I); negligence (Count III); negligent misrepresentation (Count IV); fraudulent misrepresentation (Count V); fraudulent concealment (Count VI); and fraud and deceit (Count VII).[11] Plaintiffs seek both compensatory and punitive damages.[12] Plaintiff-specific allegations are contained in individual short form complaints,[13] and this Court has ruled that any fraud-based claims must be "perfected within the short form complaints filed in the individual member cases."[14] This Court has also required the parties to submit Plaintiff and Defendant Fact Sheets.[15]

The Court denied Plaintiffs' Motion for Leave to File Plaintiffs' Third Amended Master Long-Form Complaint on December 12, 2019.[16] Plaintiffs had sought to amend the Master Complaint to no longer define PCIA as manifesting six months after chemotherapy.[17] Plaintiffs' proposed amendment alleged that there is "no single definition" for PCIA, and therefore the amount of time to establish permanent hair loss varies from patient to patient.[18] In denying Plaintiffs' motion, this Court explained that "the main reason

[9] Rec. Doc. 877 (PTO 61).
[10] Rec. Doc. 4407.
[11] *Id.* ¶¶ 221–31, 240–311.
[12] *Id.* ¶ 320.
[13] Rec. Doc. 1463 (PTO 73).
[14] *See* Hr'g Tr. at 23:4–7 (Aug. 30, 2017) (Engelhardt, J., presiding).
[15] *See* Rec. Docs. 236 (PTO 18); 326 (PTO 38); 688 (PTO 55).
[16] *See* Rec. Doc. 8702 (Order & Reasons Denying Pls.' Mot. for Leave to File Pls.' Third Am. Master Long-Form Compl. & Jury Demand).
[17] *See id.* at 2.
[18] *See id.*

Plaintiffs wish to amend the Long-Form Complaint at this juncture is to save cases that are otherwise subject to dismissal for being filed too late."[19] All deadlines for Plaintiffs to amend their individual complaints without leave of court have passed.[20]

The parties were encouraged to stipulate to direct filing and streamlined service procedures in order to expedite the process of filing and service of Short Form Complaints and avoid the costs and delays associated with removal and transfer procedures and to streamline service, which was done. The Court entered a direct filing procedure[21] and streamlined service orders.[22] Recently, the Court entered Case Management Order No. 35 (Doc. 14456) on July 26, 2022, setting a deadline of August 31, 2022 to effect service of process on all Defendants named in Plaintiffs' respective Short Form Complaints.

B. Personal Jurisdiction Over Foreign Sanofi Entities

Because two of the four Sanofi entities sued by Plaintiffs in this MDL were foreign entities based in France, the PSC sought discovery relating to personal jurisdiction over these entities and the Sanofi defendants sought dismissal of claims for lack of jurisdiction. The parties filed a "Stipulation of Terms Related to Defendants, Sanofi and Aventis Pharma S.A."[23] Pursuant to the parties' stipulation, the Court dismissed Sanofi S.A. and Aventis Pharma S.A. ("French Defendants") without prejudice.[24] Thus, whether these French Defendants may be subject to a U.S. district court's jurisdiction remains a question that might require adjudication on remand should an individual Plaintiff seek to reinstate claims against the Sanofi French Defendant entities.

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[19] *See id.* at 4.
[20] Rec. Doc. 10338 (PTO 105).
[21] See Pretrial Order Nos. 4 and 5 (Docs. 122, 131).
[22] See Pretrial Order Nos. 9, 29/29A, 30, 32/32A, 33, 39/39A, 40/40A, 83 (Docs. 160, 303, 13877, 304, 307, 710, 308, 327, 711, 328, 509, 4263).
[23] Rec. Doc. 1072.
[24] Rec. Doc. 1462 (PTO 72).

C. Case Management and Pretrial Orders

The primary orders governing pretrial management of this MDL are a series of case management orders ("CMO") and pretrial orders ("PTO"), along with certain amendments. To date, this Court has issued 63 CMOs and 150 PTOs. These orders are discussed throughout this Order and can be found on the MDL docket or this Court's website at https://www.laed.uscourts.gov/case-information/mdl-mass-class-action/taxotere.

D. Lead and Liaison Counsel

On December 28, 2016, the Court appointed Plaintiffs' Co-Lead Counsel and Plaintiffs' Executive Committee.[25] Mr. Christopher Coffin of Pendley, Baudin & Coffin LLP, in New Orleans, Louisiana, and Ms. Karen Barth Menzies of Gibbs Law Group LLP, in El Segundo, California, are Co-Lead Counsel for Plaintiffs.[26] Mr. J. Kyle Bachus of Bachus & Schanker, LLC, in Denver, Colorado, and Mr. David Miceli of Milberg Coleman Bryson Phillips Grossman, in Carrollton, Georgia, serve on the Plaintiffs' Executive Committee with Mr. Coffin and Ms. Menzies.[27] The Court appointed the Plaintiffs' Executive Committee to coordinate and manage the responsibilities of the Plaintiffs' Steering Committee ("PSC"), schedule PSC meetings, and perform any other duties ordered by the Court.[28]

The Court has also appointed Liaison Counsel.[29] Ms. Dawn Barrios of Barrios, Kingsdorf & Casteix, LLP, in New Orleans, Louisiana, and Mr. M. Palmer Lambert of Pendley, Baudin & Coffin LLP, in New Orleans, Louisiana, are Plaintiffs' Liaison Counsel.[30] Mr. Douglas Moore of Irwin Fritchie

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[25] Rec. Doc. 154 (Order Establishing Leadership Structure Within the PSC).
[26] *Id.* at 1.
[27] *Id.* The Court also appointed Ms. Dawn Barrios and Mr. M. Palmer Lambert as *ex-officio* members of the Plaintiffs' Executive Committee. *Id.* at 2.
[28] *Id.* at 1–2.
[29] Rec. Doc. 104 (PTO 2).
[30] *Id.* at 1.

Urquhart & Moore LLC, and John Olinde of Chaffe McCall, LLP, in New Orleans, Louisiana, are Defendants' Liaison Counsel.[31] Lead counsel for Sanofi are Jon A. Strongman, Harley V. Ratliff, and Adrienne L. Byard of Shook, Hardy & Bacon, LLP, in Kansas City, Missouri.[32]

E. Plaintiffs' Steering Committee and Common Benefit Fund

PTO 1 directed the selection and appointment of a PSC to conduct and coordinate the discovery stage of this litigation with Defendants.[33] The Court appointed members to the PSC on November 17, 2016.[34] The configuration of the PSC has changed during the course of the ligation,[35] as has the Court's Common Benefit Order. In February 2017, the Court entered PTO 19, which adopted the proposed Common Benefit Order submitted by Liaison Counsel and the PSC.[36] PTO 19 included an 8% holdback assessment—6% for attorneys' fees and 2% for expenses—stemming from "any and all amounts paid by defendants through settlement or pursuant to a judgment."[37] In September 2022, the Court granted the PSC's Motion to Modify PTO 19.[38] The Court increased the holdback for common benefit attorney's fees from 6% on the Gross Monetary Recovery to 15% on the Gross Monetary Recovery.[39] The Court also increased the holdback for common benefit costs from 2% on the Gross Monetary Recovery to 4.75% on the Gross Monetary Recovery.[40] The

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[31] *Id.* at 2.
[32] Contact information for the 505(b)(2) Defendants' lead counsel is available on the Court's website. *See Contacts for MDL 2740 Taxotere (Docetaxel) Products Liability Litigation*, U.S. DIST. COURT, EASTERN DIST. OF LA., https://www.laed.uscourts.gov/case-information/mdl-mass-class-action/taxotere-contacts.
[33] Rec. Doc. 4 (PTO 1).
[34] Rec. Doc. 104.
[35] Rec. Doc. 11412 (PTO 110).
[36] Rec. Doc. 262 (PTO 19).
[37] *Id.* at 24–25.
[38] Rec. Doc. 15143 (Order Granting PSC's Mot. to Modify PTO 19).
[39] *Id.* at 4.
[40] *Id.*

Court has made no findings as to the appropriate amount of any fee awards to leadership from these holdbacks.

F. Status Conferences

The Court has held regular status conferences with Lead and Liaison Counsel to advance the litigation and to resolve disputes related to various discovery and other pretrial issues. To facilitate coordination of the MDL, Liaison Counsel have filed 26 Joints Reports, which detail, among other things, case inventory, discovery, and motion practice.[41] The Court has also held in-person and remote hearings to address dipositive motion practice, the bellwether trial process, and the settlement process.

G. Settlement Committees

The Court entered PTO 6 in December 2016, which appointed a Plaintiff Settlement Committee and a Defendant Settlement Committee. The Court directed the Settlement Committees to hold regular discussions in an attempt to resolve this matter before remand of some or all of the member cases. The Settlement Committees have conferred over the course of the MDL proceedings and have held status conferences with the Court.

The first bellwether case—*Barbara Earnest v. Sanofi U.S. Services, Inc.*—was resolved after the Fifth Circuit reversed a defense verdict and remanded the case for a new trial, and it is described in more detail below. In November 2022, the Court directed the parties to engage in "bellwether" settlement negotiations in 10 cases. These negotiations resulted in resolution of five cases. Other resolution assessment work is ongoing.

H. Discovery

1. General Fact Discovery

On August 23, 2017, this Court entered CMO 5, which governed the

[41] *See, e.g.*, Rec. Doc. 14691 (Joint Report No. 26 of Liaison Counsel).

general discovery conducted in MDL 2740.[42] The General Discovery Order culminated in monthly discovery meet-and-confer calls and hearings with Magistrate Judge Michael North.[43] The Court limited Plaintiffs to 30 depositions of Sanofi witnesses, including current and former employees and corporate representatives.[44] The deadline for general discovery against Sanofi expired on December 15, 2018.[45] The Court has denied additional general discovery requests since that time.

a) Document Discovery

Document discovery was governed by CMO 5 and PTO 49, the Electronically Stored Information Protocol.[46] Sanofi disclosed information on 50 potential custodians. Plaintiffs selected 36 custodians from the United States and 7 from the European Union on which to conduct discovery. After agreeing on search terms to govern the custodians selected, Sanofi produced more than 576,100 documents (or 6,320,000 pages), which included, among other things, multiple regulatory files (both in the United States and European Union), shared files, clinical trial data, MIS files, and IMS data. Many of these documents remain subject to protective orders of confidentiality, described in Part II.G.4 below.

b) Depositions

CMO 9 governed deposition protocol.[47] It mandated coordination of federal and state proceedings to prevent witnesses from being deposed more than once.[48] In total, 28 company witnesses from Sanofi were deposed, including Sanofi's 30(b)(6) witnesses. Multiple additional Sanofi witnesses sat

[42] Rec. Doc. 762 (Case Management Order "CMO" 5).
[43] *Id.* at 2–3.
[44] *Id.* at 4.
[45] *Id.* at 5.
[46] Rec Doc. 611 (PTO 49).
[47] Rec. Doc. 1110 (CMO 9).
[48] *Id.* at 2–3.

for deposition in case-specific work up under other orders.

Each party was directed to designate one primary examiner for each deposition. Any additional examiners were not allowed to ask a witness "the same or substantially the same question" as had been previously asked by the primary examiner.[49] During the depositions, no speaking objections were allowed, and the phrase "objection as to form" (or similar language as contemplated by Rule 30(c)(2)) was sufficient to preserve all objections.[50] Any objection made at a deposition was deemed to have been made on behalf of all other parties.[51]

2. Case-Specific Discovery

a) Plaintiff Fact Sheets

In February 2017, the Court entered PTO 18, which set forth the operable Plaintiff Fact Sheet ("PFS") and Defendant Fact Sheet ("DFS").[52] The Court then entered PTO 22, which governed the implementation of the PFS and DFS.[53] PTO 22 directed each Plaintiff to serve Defendants with a complete and verified PFS, including signed Authorizations for Release of Records of all healthcare providers, using MDL Centrality.

The PFS requested each Plaintiff provide information, including but not limited to the following topics: Plaintiff's alleged injuries; the dates upon which Plaintiff was diagnosed with cancer; the chemotherapy regimen each Plaintiff received; and Plaintiff's employment, educational, and medical history.[54] The PFS required each Plaintiff to verify the accuracy and completeness of information, and the responses in the PFS were given the same legal

[49] *Id.* at 4.
[50] *Id.* at 11–12.
[51] *Id.* at 11.
[52] Rec. Doc. 236.
[53] Rec. Doc. 270 (PTO 22).
[54] Rec. Doc. 236-1 (PTO 18, Exhibit A).

significance as answers to interrogatories.[55] The Court revised the PFS in November 2017 to require Plaintiffs to produce representative photographs of their hair during designated time periods.[56]

Concerned that certain Plaintiffs in the MDL may not have "adequately and timely produced responsive electronically stored information ("ESI")" as required by the PFS, the Court entered PTO 71 in December 2017 to govern Plaintiffs' identification, preservation, collection, and production of ESI.[57] PTO 71 outlined the relevant, potential sources of ESI ("ESI Sources") Plaintiffs should search for responsive information; mandated "reasonably diligent searches" of the ESI Sources; identified search terms each Plaintiff or her attorney would run through available search functions in the ESI Sources; and required each Plaintiff to submit a written disclosure statement to Defendants to be produced along with responsive documents.[58] In January 2018, PTO 71 was amended and superseded by PTO 71A, which was identical in substance to PTO 71 but provided Plaintiffs additional time to comply with its requirements.[59]

b) Defendant Fact Sheets

After receiving a substantially completed PFS, each Defendant had 75 days to send a completed DFS to MDL Centrality.[60] Because multiple Defendants are named in individual cases, raising potential product identification issues, the Court separated the cases into three categories and

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[55] *Id.* at 31; *see also* Rec. Doc. 279 at 4 (PTO 22). The PFS was revised for typographical issues in PTO 38. Rec. Doc. 326.
[56] Rec. Doc. 1085 (PTO 68).
[57] Rec. Doc. 1306 (PTO 71).
[58] *Id.* at 1.
[59] Rec. Doc. 1531 (PTO 71A). The Court has permitted Sanofi to seek sanctions and costs in cases where Plaintiffs or their counsel have not complied with their case-specific discovery obligations. *See* Rec. Docs. 3917 (Order Granting Defs.' Mot. for Rule 37 Sanctions in *Gahan*); 12735 (Minute Entry); 12884 (Order); 13132 (Minute Entry).
[60] Rec. Doc. 279.

determined based on those categories which of the various Defendants were required to respond to a PFS and to what extent.[61] Absent product identification, Defendants were only required to produce limited information.[62]

Within the full DFS, Defendants were required to provide communications with the healthcare providers that treated the Plaintiff about Taxotere and hair loss. Defendants' responses on a DFS were given the same legal significance as responses to interrogatories and responses to requests for production of documents.[63]

c) Product Identification

On January 12, 2018, the Court entered CMO 12, later amended as CMO 12A, to enforce requirements for each Plaintiff to obtain evidence of which manufacturers' medicine she received.[64] The order created a standard form, "Statement Regarding Chemotherapy Drug Administered" for each Plaintiff to have signed by her chemotherapy infusion facility pharmacist, or other qualified custodian of record, to identify the medicine(s) used in her care by National Drug Code ("NDC").[65] Before March 2011—the period of market exclusivity of Taxotere—Sanofi manufacture was presumed, but such Plaintiffs still were required to show proof of use of Taxotere.[66] Alternatively, a Plaintiff could provide records of administration or possibly billing records identifying the medicine used in her care by NDC.[67] Under CMO 12A, Defendants were required to make their own requests in each case where the

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[61] *Id.* at 4–6.
[62] *Id.* at 6.
[63] *Id.* at 8. The DFS was revised for typographical issues in PTO 38, which was entered on April 14, 2017. Rec. Doc. 326.
[64] Rec. Docs. 1506 (CMO 12); 3492 (CMO 12A).
[65] Rec. Doc. 1506 at 2.
[66] *Id.* at 4–6. Certain conditions could create an exception, such as enrollment in a clinical trial. *Id.*
[67] *Id.* Defendants had earlier been ordered to provide charts of their NDCs and market dates, as well as their distributors. Rec. Doc. 298 at 2 (PTO 27).

Plaintiff's efforts were unavailing.[68] The Court eventually instituted a Show Cause process for Plaintiffs who had failed to undertake product identification efforts or Plaintiffs for whom such information was unavailable, had been lost, or was not maintained, after a period of potential third-party discovery of facility custodians and/or distributors.[69]

d) Photographs and Show Cause Process

Over time, the Court has gained particular expertise in evaluating photographs submitted by Plaintiffs as proof of their alleged injury. Under PTO 68, the Court required Plaintiffs to produce dated photographs that depict their hair within five years of starting chemotherapy, during chemotherapy (if available), within five years of completing chemotherapy, and recent photographs.[70] Central to the difficulty of this evaluation has been the fact that some Plaintiffs suffered a recurrence of cancer and potentially began another chemotherapy regimen. This issue dictated an additional requirement for Plaintiffs who experienced a recurrence of cancer to produce photographs

[68] Rec. Doc. 3492 at 4.

[69] Rec. Doc. 13587 (Order to Show Cause Regarding CMO-12A Product Identification). The Court deferred dismissal of "no product identification" cases in a small handful of jurisdictions (California, Illinois, and Massachusetts) that Plaintiffs argued potentially recognized "innovator" liability. Rec. Doc. 14174 at 4 (Minute Entry); *see also* Rec. Docs. 14312 (Pl.'s Show Cause Response—Innovator Liab. Under Cal. Law); 14316 (Pl.'s Show Cause Response—Innovator Liab. Under Ill. Law); 14313 (Pl.'s Show Cause Response—Innovator Liab. Under Mass. Law). In response, Sanofi asserted that 505(b)(2) manufacturers are not Abbreviated New Drug Application ("ANDA") holders for labeling purposes, that 505(b)(2) or generic manufacturers may have copied each other's labels, and that innovator liability was not pleaded in the Master Complaint or individual short form complaints, nor was it included in general or case-specific work up. Rec. Docs. 14398 (Defs.' Resp. in Opp. to Pl.'s Show Cause Response—Innovator Liab. Under Cal. Law); 14400 (Defs.' Resp. in Opp. to Pl.'s Show Cause Response—Innovator Liab. Under Ill. Law); 14399 (Defs.' Resp. in Opp. to Pl.'s Show Cause Response—Innovator Liab. Under Mass. Law).

[70] Rec. Doc. 1085 (PTO 68).

between such treatments, in order to determine whether their hair regrew before or after taking Taxotere.[71]

Apart from photograph issues, the Court issued PTO 22A on July 24, 2018, which governed Defendants' requests to dismiss the cases of Plaintiffs who allegedly failed to submit a complete and verified PFS.[72] Specifically, PTO 22A addressed Plaintiffs who failed to complete a PFS, who failed to sign authorizations, who failed to pursue or obtain product identification (as described above), who had passed away without substitution, or who had other problems of basic proof.[73] All told, the Show Cause process has resulted in dismissal of more than 3,000 cases.

e) Pathology Protocol

CMO 15 discussed pathology protocol and required Plaintiffs who had a scalp biopsy to send a preservation letter to the applicable facilities.[74] It also provided for the sharing of specimens amongst the parties, among other issues to diagnose Plaintiffs' alleged injuries.[75]

3. Expert Discovery

In June 2018, the Court entered CMO 14, which provided a schedule to identify and select Plaintiffs for a succession of bellwether trials.[76] The Court required the parties to disclose their general and specific expert reports.[77]

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[71] *See* Hr'g. Tr. 36–37 (July 9, 2021). Photographs have also been used to evaluate a Plaintiff's hair regrowth where Plaintiff began taking anti-hormonal therapy following chemotherapy.
[72] Rec. Doc. 3493 (PTO 22A).
[73] *Id.* at 1.
[74] Rec. Doc. 5008 at 1–2 (CMO 15).
[75] *Id.* at 2–3.
[76] Rec. Doc. 3064 (CMO 14).
[77] *Id.* at 2–3.

Since the first bellwether trial, several of the parties' experts have issued additional reports and have been deposed for subsequent bellwether cases.[78]

In April 2022, the Court granted the PSC's Motion to Preserve Expert Testimony[79] and later entered CMO 36. CMO 36 set out the protocols to preserve general expert testimony by video for potential use in remanded cases.[80] Under CMO 36, expert preservation deposition testimony is "subject to the Court's prior rulings as they relate to these witnesses," including the Court's Rule 702 rulings.[81] In addition, the Court did not pre-adjudicate issues related to admissibility or availability—for example, whether the parties may introduce preservation deposition testimony at trial.[82] *See* Fed. R. Evid. 804. The parties have completed the preservation depositions of two of Plaintiffs' experts. Preservation depositions, including depositions of Sanofi's experts, may continue in this Court after the entry of this Order. Further, the parties have not conducted case-specific expert discovery in the cases to be remanded, and the remand courts should set a schedule for the completion of case-specific expert discovery.

4. Protective Order and Confidentiality

A stipulated protective order governing the designation, handling, use, and disclosure of confidential discovery material was entered on July 5, 2017.[83]

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[78] The Court provides a summary of these experts and the Court's rulings on the admissibility of their opinions in Part II.J.8.
[79] Rec. Doc. 13981 (Order Granting PSC's Mot. to Preserve Expert Test.).
[80] Rec. Doc. 14925 (CMO 36).
[81] *Id.* at 1–2, 6.
[82] *Id.* at 2. If a receiving court determines that a party may introduce preservation deposition testimony at trial consistent with the Federal Rules of Evidence, the Court cautions the receiving court to analyze any proposed testimony at trial in light of this Court's Rule 702 and motions in limine rulings.
[83] Rec. Doc. 612 (PTO 50).

The Court also entered a stipulated ESI Protocol, which governed many aspects of electronically stored information.[84]

Prior to the Fifth Circuit's decision in *Le v. Exeter*, this Court routinely sealed pleadings at the parties' unopposed requests pursuant to the stipulated protective order.[85] Based on the Fifth Circuit's ruling, the Court applies the requisite particularity set forth in *Le* for sealing documents and will hear any motions to unseal documents consistent with the guidance set forth in the *Le* decision.[86] The transferor court will decide the issue on sealing of documents according to the governing law in the Circuit.

I. Bellwether Cases and Trials

On a parallel track to general discovery, the Court directed the parties to begin the case-specific workup of trial pools for bellwether trials. Initially, the Court contemplated four bellwether trials in 2019 as set forth in Case Management Order Nos. 3, 4 & 6.[87] The presiding transferee Judge Kurt D. Engelhardt was then appointed to the United States Fifth Circuit Court of Appeals and the MDL was reassigned to the Honorable Jane Triche Milazzo, who has presided as transferee Judge since May 15, 2018.[88] This Court crafted a new scheduling order that contemplated five bellwether trials comprised of both the initially selected Trial Plaintiffs and additional nominations whose claims would be adjudicated in a succession of trials.[89] Both *Lexecon* and the ability of the Court to try a case in a jurisdiction other than the Eastern District

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[84] Rec. Doc. 611.
[85] Rec. Doc. 612 (PTO 50).
[86] Binh Hoa Le v. Exeter Fin. Corp., 990 F.3d 410, 417-421 (5th Cir. 2021).
[87] Rec. Docs. 669, 670, 780.
[88] Rec. Doc. 464.
[89] *See* CMO 14 (Doc. 3064), et seq. CMO 14A (Doc. 5035), CMO 14B (Doc. 6788), CMO 14C (Doc. 6789), CMO 14D (Doc. 7416), CMO 14E (Doc. 9367), CMO 14F (Doc. 9631), CMO 14G (Doc. 10985), CMO 14H (Doc. 11392), CMO 14I (Doc. 12283), CMO 14J (Doc. 12760), CMO 14J (Doc. 13195), CMO 14K (Doc. 13199), CMO 14L (Doc. 13298), CMO 14M (Doc. 13468), CMO 14N (Doc. 14240).

of Louisiana were forefront in the nomination or selection of bellwether Plaintiffs.

Following completion of limited "Phase I" discovery, four trial Plaintiffs were selected by the Court for the first trial, and deadlines for pre-trial matters such as general and specific expert reports, the exchange of "materials relied upon", depositions, briefing schedule for dispositive or Daubert Motions, and the schedule for trial preparation documents, and setting the trial date were set. Based on the submission to the Court by Sanofi and Plaintiffs, the Court selected additional Plaintiffs for the next trial pools, as well as setting forth the procedure for the nomination of trial Plaintiffs following completion of Phase I bellwether workup. The Court emphasized that the nominated trial Plaintiffs must be representative of the characteristics of the claims in the MDL. The Court intended to hold five trials – three involving Sanofi (including one where the Court would sit by designation in Mississippi), and two involving the 505(b)(2) defendants. Ultimately, two Louisiana Plaintiffs' cases involving Sanofi proceeded as bellwether trials.

The first bellwether trial (*Earnest v. Sanofi*) was held in September 2019. The jury found in favor of the defense.[90] The Plaintiffs appealed, and the Fifth Circuit Court of Appeals reversed and returned the case to the district court.[91] On remand, with motion practice pending, the *Earnest* matter resolved in settlement in 2022.

The second bellwether trial (*Kahn v. Sanofi*) proceeded in November 2021 and the jury returned a defense verdict.[92] The plaintiff has sought Rule 60(b) relief given her position that pretrial rulings similar to those in *Earnest*

[90] Doc. 8284.
[91] *In re* Taxotere (Docetaxel) Prod. Liab. Litig., 26 F.4th 256 (5th Cir. 2022).
[92] Doc. 13436.

prejudiced her ability to fairly present evidence in her trial. That motion remains pending.

J. Wave Workup

In CMO 33, the Court began the process of remanding and/or transferring the cases still pending in the MDL to their appropriate trial courts.[93] CMO 33 outlined the process for selection and discovery of the first 200 cases, which became the "Wave 1" cases.[94] Wave 1 was limited to cases where the Plaintiffs had identified in their PFS only brand name Taxotere and/or Winthrop.[95] Wave 1 selection criteria also included the following: no cases involving deceased Plaintiffs; no cases where treatment took place either before December 15, 2006, or after December 11, 2015; and no cases where the Plaintiff was prescribed or administered Taxotere in Michigan, Louisiana, Mississippi, or Texas.[96] CMO 34 listed the selected cases.[97]

Discovery in Wave 1 was limited to certain supplemental discovery and up to four depositions, including (1) Plaintiff; (2) Plaintiff's prescribing physician; (3) Plaintiff's treating physician (if any); and (4) one sales representative who called on Plaintiff's healthcare provider.[98]

On June 13, 2022, after an initial hearing and challenges to case eligibility, the Court re-categorized the cases in Wave 1 into (1) cases proceeding with Wave 1 remand discovery and (2) cases not proceeding with Wave 1 remand discovery.[99] In CMO 34B, issued on August 26, 2022, the Court

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[93] Rec. Doc. 13946 (CMO 33).
[94] *Id.*
[95] *Id.* at 2.
[96] *Id.* at 2–3. Cases where the Plaintiff was prescribed or administered Taxotere in Michigan has previously been dismissed on state-law grounds. *See* Rec. Doc. 13327 (Minute Order) (dismissing with prejudice 355 cases from Michigan pursuant to the Michigan Products Liability Act).
[97] Rec. Doc. 14045 (CMO 34).
[98] Rec. Doc. 13946 at 5.
[99] Rec. Doc. 14292 (CMO 34A).

designated cases as either Plaintiff or Sanofi-priority cases for purposes of physician deposition scheduling and examination order.[100] And on February 23, 2023, this Court entered CMO 34C, which reflected only 98 cases proceeding with Wave 1 discovery and extended the deadline for completing Wave 1 discovery to February 28, 2023.[101]

K. Key Legal and Evidentiary Rulings

1. Fencepost Rulings

In early 2020, Sanofi filed two "fencepost motions"[102]—motions for summary judgment seeking dismissal of cases where Plaintiffs were treated with Taxotere before December 15, 2006 ("pre-2007 motion")[103] and after December 2015 ("post-2015 motion").[104] With respect to the pre-2007 motion, Sanofi argued for dismissal because Plaintiffs' regulatory expert (Dr. David Kessler, former FDA Commissioner) opined that Sanofi should have warned of permanent alopecia as of December 2006.[105] The pre-2007 motion related to approximately 1,400 cases.[106] The Court, recognizing some differences between state laws, elected to analyze the issue with respect to Louisiana Plaintiffs by way of example.[107] The Court held that the Louisiana Plaintiffs failed to create a genuine issue of material fact supporting their pre-2007 claims because they could not prove Sanofi had "knowledge" that Taxotere potentially caused

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[100] *Id.* at 2.
[101] Rec. Doc. 15547 (CMO 34C).
[102] The Court uses the term "fencepost motions" to describe motions that set parameters for groups of cases contained in the MDL. In this instance, there was a pre-2007 fencepost motion and a post-2015 fencepost motion.
[103] Rec. Doc. 8977 (Defs.' Mot. for Summ. J. on the Claims of Pls. Whose Taxotere Treatment Started Before December 15, 2006) ("Pre-2007 Mot.").
[104] Rec. Doc. 9268 (Defs.' Mot. for Summ. J. on the Claims of Pls. Whose Taxotere Treatment Started After December 11, 2015) ("Post-2015 Mot.").
[105] Rec. Doc. 8977-2 at 5–13 (Mem. in Supp. of Defs.' Pre-2007 Mot. for Summ. J.).
[106] Rec. Doc. 8977-3 (Exhibit A to Defs.' Pre-2007 Mot. for Summ. J.).
[107] Rec. Doc. 10487 at 4–5 (Order Granting in Part and Deferring in Part Defs.' Pre-2007 Mot. for Summ. J.).

permanent alopecia before December 2006.[108] The Court dismissed the Louisiana cases and instructed the parties to submit supplemental briefing on which states have similar requirements as Louisiana, which has been completed.[109]

With respect to the post-2015 motion, Sanofi argued that its labeling as of December 2015, which warned that "cases of permanent alopecia have been reported," was adequate as a matter of law because the label clearly and accurately described permanent alopecia as a known risk of Taxotere.[110] This motion related to approximately 200 cases.[111] The Court held that the Taxotere label after December 2015 adequately warned of permanent alopecia, and the Court granted summary judgment on Plaintiffs' failure-to-warn claims.[112]

2. Preemption

The Court has ruled on two preemption motions filed by Sanofi in the MDL. These motions turned on the issue of impossibility preemption—that is, whether it was impossible for Sanofi to have updated its label under the Federal Food, Drug, and Cosmetic Act before certain Plaintiffs' dates of treatment. Before Ms. Earnest's bellwether case, the Court denied in part and deferred in part Sanofi's summary judgment motion based on preemption.[113] Sanofi asserted that at the time Ms. Earnest received Taxotere in 2011, federal law prevented Sanofi from unilaterally adding different warning language to the Taxotere labeling.[114] The Court, however, found that Sanofi had not shown any attempt to update its labeling through the federal Change Being Effected

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[108] *Id.* at 7–9.
[109] *Id.* at 9–10.
[110] Rec. Doc. 9268-2 at 7–14 (Mem. in Supp. of Defs.' Post-2015 Mot. for Summ. J.).
[111] Rec. Doc. 9268-3 (Exhibit A to Defs.' Post-2015 Mot. for Summ. J.).
[112] Rec. Doc. 10464 at 5–6 (Order Granting Defs.' Post-2015 Mot. for Summ. J.).
[113] Rec. Doc. 7973 (Order Denying in Part and Deferring in Part Defs.' Mot. for Summ. J. Based on Preemption in *Earnest*). The Court deferred ruling on preemption as it related to other Plaintiffs in the MDL.
[114] *Id.* at 2.

regulation, nor did Sanofi present "clear evidence" that the FDA would not have approved a change to the Taxotere label.[115] The Court considered evidence Sanofi had submitted to FDA in 2004 and 2009, but it did not find that "Sanofi was trying to alert the FDA of an uptick in reports of permanent alopecia."[116]

Before Ms. Kahn's bellwether trial, the Court granted in part and denied in part Sanofi's summary judgment based on preemption.[117] Sanofi asserted that it could not update its label before Ms. Kahn's treatment in 2008.[118] Specifically, Sanofi identified the results of two clinical trials and two scientific publications that Sanofi had provided to FDA before 2004 that, according to Sanofi, "disclosed data and reports of alopecia, including reports of patients with ongoing, persistent, or nonreversible alopecia following treatment with combination chemotherapy regimens that included Taxotere."[119] The Court, however, found that an abstract published in 2006 constituted "newly acquired information" that would have supported a label change under the federal Changes Being Effects regulation.[120] The Court then analyzed the "clear evidence" prong of the impossibility preemption framework. The Court held federal law preempted Ms. Kahn's claim that Sanofi should have included permanent alopecia in the Warnings and Precautions section of the Taxotere label because there was clear evidence FDA would have rejected such a claim based on communications between Sanofi and FDA in 2015.[121] Based on these rulings, the Court permitted Ms. Kahn to proceed with a claim that Sanofi

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[115] *Id.* at 8.
[116] *Id.* at 9.
[117] Rec. Doc. 11682 (Order Granting in Part and Denying in Part Defs.' Mot. for Summ. J. Based on Preemption in *Kahn*).
[118] *Id.* at 14.
[119] *Id.*
[120] *Id.* at 19.
[121] *Id.* at 20–21.

should have updated the Adverse Reactions section of the Taxotere label to include the language later approved in 2015, back at the time of Ms. Kahn's treatment.[122]

3. Proof of Diagnosis

In July 2020, Sanofi filed a Motion for Entry of an Order Requiring Proof of Diagnosis.[123] The proposed order would have required each Plaintiff to submit either evidence of a medical diagnosis of PCIA caused by Taxotere or state that Plaintiff did not intend to pursue such a diagnosis.[124] Approximately 80 percent of MDL Plaintiffs do not have medical evidence of their alleged hair loss injury or causation.[125] Following a lead and liaison conference in August 2020, the Court deferred ruling on Sanofi's motion, subject to being re-urged after the third bellwether trial.[126] After the Court dismissed the third bellwether Plaintiffs, Sanofi re-urged its motion in February 2022.[127] The Court, however, entered CMO 33 in March 2022, which began Wave 1 work-up.[128]

4. General Causation

This Court has also addressed general causation as it relates to both bellwether trials.[129] To prevail on their claims, Plaintiffs must establish general causation through reliable expert testimony.[130] General causation

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[122] *Id.* at 21–22.
[123] Rec. Doc. 10808 (Defs.' Mot. for Entry of an Order Requiring Proof of Diagnosis).
[124] *Id.* at 1.
[125] Rec. Doc. 10808-1 at 1 (Mem. of Law. in Supp. of Defs.' Mot. for Entry of an Order Requiring Proof of Diagnosis). PCIA requires a differential diagnosis. *Id.* at 5–9.
[126] Rec. Doc. 10908 (Order Deferring Defs.' Mot. for Entry of an Order Requiring Proof of Diagnosis).
[127] Rec. Doc. 13912 at 5 (Defs.' Remand Proposal).
[128] Rec. Doc. 13946.
[129] Rec. Docs. 8094 (Order and Reasons Denying Mot. to Exclude Expert Test. on General Causation in *Earnest*); 11685 (Order and Reasons Denying Pl.'s Motion for Partial Summ, J. on Causation in *Kahn*).
[130] Rec. Doc. 8094 at 5.

requires a Plaintiff to meet a two-pronged test under Louisiana law: (1) there must be evidence showing a "statistically significant association" between the agent and the disease, and (2) there must be a causal relationship that underlies the association.[131]

In Ms. Earnest's case, Sanofi argued that Plaintiff had failed to establish general causation because Plaintiff's experts, Dr. Madigan and Dr. Feigal, did not analyze or set out a methodology in their expert reports that would be sufficient to establish general causation.[132] This Court held that Plaintiff had presented evidence to establish both prongs by relying on Dr. Madigan to identify a statistically significant association between Taxotere and the alleged injury, and Dr. Feigal to establish a causal association using the Bradford Hill criteria.[133]

In Ms. Kahn's case, Plaintiff sought partial summary judgment, requesting this Court find as a matter of law that "Taxotere can cause permanent alopecia."[134] Plaintiff argued that because Sanofi communicated to FDA in 2015 that enough evidence existed to support a "causal association" between Taxotere and permanent alopecia and because of Dr. Madigan and Dr. Feigal's testimony, no reasonable jury could find that Taxotere does not cause permanent hair loss.[135] The Court disagreed, noting that that the 2015 correspondence between FDA and Sanofi was not an admission of causation and that Sanofi had provided its own experts who presented "reliable evidence to rebut Plaintiff's contentions."[136]

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[131] *Id.* at 5.
[132] Rec. Doc. 6163 (Defs.' Mot. to Exclude Expert Test. on General Causation in *Earnest*).
[133] Rec. Doc. 8094 at 5–6. The Bradford Hill criteria are: (1) temporal relationship; (2) strength of the association; (3) dose-response relationship; (4) replication of findings; (5) biological plausibility; (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge. *Id.* at 5.
[134] Rec. Doc. 11685 at 2.
[135] *Id.* at 3.
[136] *Id.*

Accordingly, in both bellwether trials, this Court held that general causation could not be determined as a matter of law and therefore should be decided by the jury after hearing the testimony of each party's experts.

5. Statute of Limitations

The Court has addressed numerous statute of limitations motions over the course of the MDL, and the Fifth Circuit has also considered several appeals on the statute of limitations.[137]

In July 2019, the Court ruled on motions for summary judgment based on the statute of limitations in three bellwether cases under Louisiana law.[138] In Louisiana, the statute of limitations for products liability claims is one year.[139] The Court first looked to Plaintiffs' Master Complaint, which defined the injury of permanent alopecia as manifesting six months after the completion of chemotherapy.[140] In each case, Plaintiffs filed their lawsuits in 2016—several years after completing chemotherapy—after learning of the link between Taxotere and permanent alopecia through advertisements and social media.[141] Because Plaintiffs' claims were time-barred on their face, the Court next considered whether the Louisiana doctrine of *contra non valentem* (or the "discovery rule") applied, which states that the statute of limitations begins to run when a plaintiff has "actual or constructive knowledge of facts indicating to a reasonable person that he or she is a victim of a tort."[142]

In Plaintiff Deborah Johnson's case, the Court reasoned that Ms. Johnson completed her chemotherapy in 2010 and testified that she did not think anything other than her chemotherapy caused her hair loss and that she

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[137] Part II.J.7 provides an overview of the appellate decisions on statute of limitations.
[138] Rec. Doc. 7571. Three of the motions requested summary judgment based on the learned intermediary doctrine. *Id.* at 1.
[139] *Id.* at 4 (citing La. Civ. Code Art. 3492).
[140] *Id.* at 2–3.
[141] *Id.* at 3.
[142] *Id.* at 5.

became very concerned that her hair might not grow back at all as early as 2010.[143] Finding no evidence that Ms. Johnson investigated her injury before filing her lawsuit in 2016, the Court granted summary judgment in Sanofi's favor.[144] Likewise, in Plaintiff Tanya Francis's case, the Court found that Ms. Francis's allegations made "clear that she recognized the severity of her symptoms and that she attributed her hair loss to her chemotherapy."[145] Because Ms. Francis had a duty to investigate and failed to do so, the Court held that the *contra non valentem* doctrine did not apply and her claims were time-barred.[146]

The Court denied summary judgment on the statute of limitations in Plaintiff Barbara Earnest's case.[147] The Court distinguished Ms. Earnest's case, finding that she inquired with her doctor about her injury and was led to believe that her hair was just taking more time to regrow, until 2016.[148] As a result, an issue of fact remained for the jury to decide, and Ms. Earnest's case proceeded as the first bellwether trial.

In January 2020, the Court granted summary judgment on the statute of limitations in Plaintiff Cynthia Thibodeaux's case.[149] Ms. Thibodeaux completed chemotherapy in June 2009, and the Master Complaint defined her injury of PCIA as manifesting six months after chemotherapy.[150] Because the one-year limitations period ended in January 2011, the Court held that Ms. Thibodeaux's case filed in October 2016 was time-barred on its face.[151] The

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[143] *Id.* at 6.
[144] *Id.* at 6, 26.
[145] *Id.* at 10.
[146] *Id.*
[147] *Id.* at 8.
[148] *Id.*
[149] Rec. Doc. 9110 (Order Granting Defs.' Mot. for Summ. J. in *Thibodeaux*).
[150] *Id.* at 4–5.
[151] *Id.* at 5.

Court also held that the *contra non valentem* doctrine was inapplicable.[152] Ms. Thibodeaux "had actual or constructive knowledge of a causal relationship between her injury and Taxotere, yet she did nothing to investigate."[153]

In April 2020, the Court denied summary judgment on the statute of limitations in Plaintiff Elizabeth Kahn's case, which proceeded as the second bellwether trial.[154] Although the Court found that Ms. Kahn's case was time-barred on its face, the Court held that there was an issue of fact under the *contra non valentem* doctrine.[155] Specifically, the Court found that Ms. Kahn may have had reason to believe that something other than Sanofi's conduct caused her injury because Ms. Kahn's gynecologist told Ms. Kahn that her hair loss may be due to age.[156]

In July 2020, the Court granted summary judgment on the statute of limitations under Louisiana law in Plaintiff Antoinette Durden's case.[157] The Court held that Ms. Durden's case was time-barred on its face.[158] The Court further found that Ms. Durden "suspected something was wrong and yet failed to investigate its cause."[159] Although Ms. Durden sought treatment from her doctors for her hair loss, the Court found that this alone was insufficient.[160] Without evidence showing that any of Ms. Durden's doctors told her, after her treatment, that regrowth can take time or that something else was causing her injury, the *contra non valentem* doctrine did not apply.[161]

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[152] *Id.*
[153] *Id.*
[154] Rec. Doc. 9885 (Order Denying Defs.' Mot. for Summ. J. Based on the Statute of Limitations in *Kahn*).
[155] *Id.* at 6.
[156] *Id.* at 7–8.
[157] Rec. Doc. 10833 (Order Granting Defs.' Mot. for Summ. J. in *Durden*).
[158] *Id.* at 3.
[159] *Id.* at 5.
[160] *Id.*
[161] *Id.* at 5–6.

The Court has also issued statute of limitations rulings under Mississippi law. In January 2021, the Court granted Sanofi's motion for judgment on the pleadings and dismissed Plaintiff Juanita Greer's case, finding her claims were time-barred by the three-year statute of limitations under Mississippi law.[162] The Court rejected Ms. Greer's argument that the discovery rule and the fraudulent concealment exception applied to toll the statute of limitations in her case.[163] Specifically, the Court held that the discovery rule only applied to cases involving latent injuries under Mississippi law. Because the pleadings established Ms. Greer's injury was open and obvious, the discovery rule could not toll her claims.[164] The Court further held that the fraudulent concealment exception did not apply because Ms. Greer did not plead that Sanofi prevented her from discovering her claim, as required by Mississippi law, but rather that Sanofi prevented her from discovering Taxotere's risk of permanent hair loss.[165]

The Court later granted Sanofi's motions for summary judgment in Plaintiffs Melissa Roach and Cindy Smith's cases for the reasons articulated in Ms. Greer's case.[166] Following a show cause process, the Court dismissed the claims of 223 Mississippi Plaintiffs under the statute of limitations.[167] Sanofi urged 12(c) motions in five additional states—Alabama, Idaho, North Carolina, North Dakota, and Virginia—citing the absence of any discovery rule in those

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[162] Rec. Doc. 12057 (Order Granting Defs.' Mot. for J. on the Pleadings Based on the Statute of Limitations in *Greer*).
[163] *Id.*
[164] *Id.* at 6.
[165] *Id.* at 8.
[166] Rec. Docs. 12718 (Order Granting Defs.' Mot. for Summ. J. Based on the Statute of Limitations in *Roach*); 13064 (Order Granting Defs.' Mot. for Summ. J. Based on the Statute of Limitations in *Smith*).
[167] Rec. Doc. 15322 (Order Denying Mot. for Recons. by Pls. Whose Cases Were Dismissed by this Court's Orders of July 13, 2022 and July 18, 2022).

states, which the Court denied without prejudice.[168]

6. Warnings Causation

Warnings causation has also played in a prominent role in bellwether motion practice. The Court summarizes several key decisions below. In addition, the Fifth Circuit Guidance section provides appellate decisions on warnings causation.

In Ms. Earnest's case, the Court denied Sanofi's motion for summary judgment based on warnings causation in July 2019.[169] Under Louisiana law, inadequate warning claims are governed by a two-prong test.[170] The plaintiff must first show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product not otherwise known to the physician.[171] Second, the plaintiff must show that the failure to warn was both the cause in fact and proximate cause of the plaintiff's injury.[172] The Court noted that Ms. Earnest's oncologist testified that he could choose either Taxotere or Taxol to treat Ms. Earnest.[173] Based on Ms. Earnest's testimony that she would have relied on her oncologist to prescribe an equally effective drug as Taxotere if she had the option, the Court found that the oncologist and Ms. Earnest's testimony created an issue of fact on whether Ms. Earnest would have still chosen Taxotere despite knowing of its risks of permanent alopecia.[174]

The Court granted Sanofi's motion for summary judgment on warnings

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[168] Rec. Doc. 14207 (Order Denying Without Prejudice Defs.' Mot. for J. on the Pleadings as to the Claims of Beverly Dickerson, Catherine Hurrell, Annie Johnson, JoAnn Coates, and Margaret Bailey).
[169] Rec. Doc. 7571 at 20 (*Earnest*).
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] *Id.* at 20–21.
[174] *Id.* at 21.

causation in Plaintiff Kelly Gahan's case in March 2020.[175] Deciding the issue under Colorado law, the Court dismissed Ms. Gahan's failure-to-warn claims, finding that Ms. Gahan was aware of the risk of permanent hair loss and nonetheless proceeded with a Taxotere regimen.[176] As a result, the Court held that Ms. Gahan had failed to create an issue of fact on whether her oncologist's prescribing decision would have changed had Sanofi provided a different warning.[177]

In April 2020, the Court denied Sanofi's motion for summary judgment on warnings causation in Ms. Kahn's case.[178] The Court found that Ms. Kahn's oncologist testified that he would discuss other chemotherapy options with a patient if she did not wish to take Taxotere after learning of a potential risk of permanent hair loss and that Taxol was an adequate alternative in terms of efficacy.[179] In addition, Ms. Kahn testified that, had she been aware of the risk, she would have asked what her other options were.[180] Taken together, the Court held that there were fact issues for the jury to decide on warnings causation.[181] Following a decision by the Fifth Circuit on warnings causation in Plaintiff June Phillips's case, Sanofi moved for reconsideration of this Court's order in Ms. Kahn's case, which the Court denied.[182]

The Fifth Circuit's decision in Ms. Phillips's case affirmed this Court's grant of summary judgment on warnings causation in April 2020.[183] In Ms. Phillips's case, her oncologist testified that there were no adequate non-

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[175] Rec. Doc. 9440 (Order Granting Defs.' Mot. for Summ. J. Based on the Learned Intermediary Doctrine in *Gahan*).
[176] *Id.* at 8.
[177] *Id.*
[178] Rec. Doc. 9888 (*Kahn*).
[179] *Id.* at 4–5.
[180] *Id.* at 5.
[181] *Id.*
[182] Rec. Doc. 13062 (Order Denying Defs.' Mot. for Recons. on Warnings Causation).
[183] Rec. Doc. 9887 (*Phillips*).

Taxotere regimens to treat Ms. Phillips's aggressive cancer.[184] As a result, this Court held that even with an adequate warning, the evidence demonstrated that Ms. Phillips and her oncologist would have decided on a Taxotere regimen to treat her cancer.[185]

In July 2020, in Plaintiff Antoinette Durden's case, the Court denied summary judgment on warnings causation grounds.[186] The Court held that the evidence suggested that Ms. Durden's oncologist would have warned Ms. Durden of Taxotere's risks, and she would have discussed and respected any concerns that Ms. Durden had about the risks.[187] As a result, the Court found that warnings causation was a question for the jury.[188]

The Court granted Sanofi's motion for summary judgment on warnings causation in Plaintiff Emma Willie's case in April 2021.[189] Applying Mississippi law, the Court found that Ms. Willie's oncologist would still have recommended today the same Taxotere-containing regimen that he recommended to her in 2014.[190] And based on Ms. Willie's testimony that she was focused on survival and trusted her oncologist, the Court concluded that "a reasonable jury could only find that Willie would not have gone against [her oncologist's] recommendation to take a Taxotere-containing regimen, even if it meant risking permanent hair loss."[191]

7. Michigan Cases

At defendants' request, the Court entertained a non-bellwether motion for summary judgment in a single case of defendants' choosing where

[184] *Id.* at 4.
[185] *Id.* at 6.
[186] Rec. Doc. 10832 (Order Granting in Part and Denying in Part Defs.' Mot. for Summ. J. Based on the Learned Intermediary Doctrine in *Durden*).
[187] *Id.* at 6–7.
[188] *Id.* at 7.
[189] Rec. Doc. 12491 (*Willie*).
[190] *Id.* at 4.
[191] *Id.* at 8.

Michigan's product liability law applied with the caveat that the ruling would be applied generally for Michigan cases. The Court granted summary judgment, finding the Michigan Products Liability Act precluded the Plaintiff's claim.[192] The Court held a show cause proceeding in which Plaintiffs were required to appear and show cause why the *Mixon* ruling did not preclude their action where Michigan substantive law applied.[193] Some Plaintiffs objected on choice-of-law grounds. Those issues have been deferred for the transferor courts to determine.[194]

8. Fifth Circuit Guidance

The Fifth Circuit has also issued decisions addressing appeals from the MDL, primarily on statute of limitations and warnings causation issues.

On April 19, 2021, the Fifth Circuit affirmed this Court's dismissal of Ms. Phillips's case based on warnings causation.[195] The Fifth Circuit held that there was insufficient evidence to create a dispute as to whether a warning for permanent alopecia would have changed Ms. Phillip's doctor's prescribing decision.[196] Ms. Phillips's prescribing physician testified that he would have recommended the same treatment for Ms. Phillips even if the label had included a warning for permanent alopecia.[197] The Fifth Circuit further clarified the application of warnings causation under Louisiana law, declining to adopt Ms. Phillips's argument that it should consider whether the Plaintiff's role in treatment would have changed the prescribing physician's counseling—as opposed to his or her recommendation—upon learning about permanent alopecia.[198] Ms. Phillips filed a petition for *en banc* review of the Fifth Circuit's

[192] *See* Order and Reasons in *Mixon* (Doc 12405).
[193] Doc. 13327.
[194] Doc. 14454.
[195] *In re* Taxotere (Docetaxel) Prods. Liab. Litig. (Phillips), 994 F.3d 704, 706 (5th Cir. 2021).
[196] *Id.* at 709.
[197] *Id.*
[198] *Id.* at 708–09.

decision on May 3, 2021, which was denied.[199]

On April 21, 2021, the Fifth Circuit affirmed this Court's dismissals of the claims of Ms. Francis, Ms. Thibodeaux, and Ms. Johnson based on the statute of limitations.[200] The Fifth Circuit held that the three Plaintiffs' claims were facially prescribed and that *contra non valentem* did not toll Plaintiffs' claims because they did not act reasonably in failing to investigate their claims.[201] The Fifth Circuit stated, "[a] reasonable inquiry into the cause of one's persistent hair loss would likely include consultation with doctors, but a plaintiff with persistent hair loss might instead search for the cause herself."[202] The Fifth Circuit also highlighted a number of internet sources, medical literature, and news articles discussing persistent alopecia associated with Taxotere that were available to Plaintiffs before their claims expired.[203] On May 5, 2021, Plaintiffs sought *en banc* review of the decision, which was denied.[204]

On June 9, 2021, the Fifth Circuit affirmed this Court's dismissal of Ms. Durden's claims on statute of limitations grounds.[205] Following its decision in *Thibodeaux*, the Fifth Circuit found that Ms. Durden had sustained her injury six months after chemotherapy.[206] The Fifth Circuit further held that that *contra non valentem* did not apply in Ms. Durden's case because she "never

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[199] Appellant's Pet. Reh'g En Banc, *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Phillips)*, No. 20-30405 (5th Cir. May 3, 2021); Denial of Reh'g En Banc, *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Phillips)*, No. 20-30405 (5th Cir. May 24, 2021).
[200] *In re* Taxotere (Docetaxel) Prods. Liab. Litig. (Thibodeaux), 995 F.3d 384, 387 (5th Cir. 2021).
[201] *Id.* at 392–94.
[202] *Id.* at 393.
[203] *Id.* at 393–94.
[204] Appellants' Pet. for Reh'g En Banc, *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Thibodeaux)*, No. 20-30104 (5th Cir. May 5, 2021); Denial of Reh'g En Banc, *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Thibodeaux)*, No. 20-30104 (5th Cir. June 1, 2021).
[205] *In re* Taxotere (Docetaxel) Prods. Liab. Litig. (Durden), 860 F. App'x 886, 887 (5th Cir. 2021).
[206] *Id.* at 890–91.

explored' Taxotere as a possible explanation for her persistent hair loss."[207]

On July 1, 2021, the Fifth Circuit affirmed this Court's dismissal of Ms. Gahan's clams.[208] The Fifth Circuit reasoned that Ms. Gahan could not establish that Sanofi's alleged failure to warn was a proximate cause of her injury.[209] Because both Ms. Gahan and her doctor were specifically aware of the risk of permanent hair loss before Ms. Gahan received Taxotere, the Fifth Circuit held that "[a] reasonable person, with all of the information that Gahan possessed, would not have changed her mind by reading a warning that told her what she already knew."[210]

9. Rule 702 Rulings

a) Plaintiffs' Experts

The Court assessed the opinions of Plaintiffs' experts under Rule 702 before both bellwether trials. In *Earnest*, Plaintiff called at trial Dr. David Kessler, Dr. David Madigan, Dr. Laura Plunkett, Dr. Antonella Tosti, Dr. Ellen Feigal, and Dr. Linda Bosserman. In *Kahn*, Plaintiff called at trial Dr. Linda Bosserman, Dr. Antonella Tosti. Dr. Laura Plunkett, Dr. Ellen Feigal, and Dr. David Madigan.

David Madigan, PhD. Dr. David Madigan is a biostatistician who the Court permitted to opine on whether there was a statistically significant association between Taxotere and PCIA (the first prong of general causation).[211] The Court found Dr. Madigan's methods—including his search

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[207] *Id.* at 892 (cleaned up).
[208] *In re* Taxotere (Docetaxel) Prods. Liab. Litig. (Gahan), 859 F. App'x 692, 695 (5th Cir. 2021).
[209] *Id.* at 694.
[210] *Id.*
[211] Rec. Docs. 8094 at 4–7 (Order Denying Defs.' Mot. to Exclude Expert Test. on General Causation, Denying Defs.' Mot. to Exclude Expert Test. of Madigan, and Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Feigal in *Earnest*); 12098 at 1–2, 4–5 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Madigan in *Kahn*).

of the FDA's adverse event report database and Sanofi's internal pharmacovigilance database and his statistical analysis of Sanofi's clinical studies TAX 316 and TAX 301/GEICAM 9805—passed muster.[212] The Court also allowed Dr. Madigan to opine that a safety signal, defined as "a concern about an excess of adverse events compared to what would be expected to be associated with a product's use," emerged in 2000 and 2008, or "several years earlier" than 2015.[213]

The Court, however, precluded Dr. Madigan from opining that Taxotere actually causes PCIA (the second prong of general causation).[214] Dr. Madigan did not conduct a Bradford Hill analysis to demonstrate medical causation.[215] In *Kahn*, the Court also limited Dr. Madigan's testimony on Sanofi's internal database: Dr. Madigan could only refer to a reporting rate, not an incidence rate, of Taxotere patients who experienced permanent alopecia.[216] Last, Dr. Madigan was not permitted to testify about his meta-analysis of four observational studies because in practice he discouraged them in similar circumstances.[217]

Ellen Feigal, M.D. Dr. Ellen Feigal is an oncologist with experience in clinical trials, pharmacological product development, and pharmacovigilance.[218] The Court allowed Dr. Feigal to opine that Taxotere causes PCIA (the second prong of general causation).[219] To support her opinion,

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[212] Rec. Docs. 8094 at 8–10 (*Earnest*); 12098 at 6–14 (*Kahn*).
[213] Rec. Doc. 8094 at 10–11 (*Earnest*) (quoting Rec. Doc. 6144 at 4 (Mem. in Supp. of Defs.' Mot. to Exclude Expert Test. of Madigan)).
[214] Rec. Docs. 8094 at 6 (*Earnest*); 12098 at 4–6 (*Kahn*).
[215] Rec. Docs. 8094 at 5 (*Earnest*); 12098 at 4–6 (*Kahn*).
[216] Rec. Doc. 12098 at 10–11 (*Kahn*).
[217] Rec. Docs. 12098 at 12–13 (*Kahn*); 12403 at 3–4 (Order Denying Pl.'s Mot. to Recons. Order Regarding Madigan's Meta-Analysis of Observational Studies in *Kahn*).
[218] Rec. Doc. 11810 at 1–2 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Feigal in *Kahn*).
[219] Rec. Docs. 8094 at 5–8, 11–17 (*Earnest*); 11810 at 6 (*Kahn*).

Dr. Feigal relied on Dr. Madigan's statistical analysis, an adverse event report Sanofi prepared for FDA, medical literature, and Sanofi's clinical studies evaluating ongoing alopecia.[220]

The Court also permitted Dr. Feigal to offer general testimony on the following topics: the standard of care in the informed consent process, how pharmaceutical companies disseminate risk information, and treatment alternatives to Taxotere.[221] The Court, however, precluded Dr. Feigal from offering case-specific testimony.[222] Dr. Feigal, for example, could not opine on what a reasonable physician would have done with a warning about PCIA.[223] The Court reasoned that this testimony would imply that Sanofi's warning was inadequate when the Plaintiffs' treating physicians were available to testify about whether a different warning would have affected their prescribing decisions.[224]

Linda Bosserman, M.D. Dr. Linda Bosserman is a board-certified clinical oncologist who specializes in breast cancer.[225] The Court permitted Dr. Bosserman to offer general testimony on the following topics: medical guidelines and the standard of care for informed consent; the benefits and current use of online tools that predict the success of different chemotherapy treatments; how pharmaceutical companies disseminate risk information to physicians; the use of cooling caps to prevent hair loss; and the non-Taxotere treatment regimens available when the Plaintiff underwent treatment.[226]

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[220] Rec. Doc. 8094 at 5–8, 11–12 (*Earnest*).
[221] *Id.* at 17–19; Rec. Doc. 11810 at 5–6 (*Kahn*).
[222] Rec. Doc. 8094 at 18–19 (*Earnest*).
[223] Rec. Doc. 11810 at 6 (*Kahn*).
[224] Rec. Docs. 8094 at 18 (*Earnest*); 11810 at 5–6 (*Kahn*).

[225] Rec. Docs. 7807 at 1–2 (Order Granting in Part Defs.' Mot. to Exclude Expert Test. of Bosserman in *Earnest*); 12109 at 1–2 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Bosserman in *Kahn*).

[226] Rec. Docs. 7807 at 5–7 (*Earnest*); 12109 at 6–7, 9 (*Kahn*).

While the Court permitted Dr. Bosserman to provide general testimony on these topics, it precluded her from testifying about how they applied to the facts in a given Plaintiff's case. Accordingly, Dr. Bosserman could not testify about how a different warning from Sanofi would have affected the prescribing physician's treatment recommendation.[227] Dr. Bosserman also could not testify on Ms. Kahn's preferences and quality-of-life concerns when Ms. Kahn and her physicians were available to testify on those matters.[228] Dr. Bosserman also could not testify about how online predictive tools would apply in the Plaintiffs' cases.[229]

The Court also prohibited Dr. Bosserman from testifying on what Sanofi, the writers of the informed consent form for Ms. Kahn's clinical trial,[230] or Ms. Kahn's medical providers knew about the risk of PCIA associated with Taxotere.[231] The Court found that Dr. Bosserman offered no support for her opinions on knowledge and that, to the extent she relied on the opinions of Dr. Feigal, she did not validate Dr. Feigal's opinion.[232]

Antonella Tosti, M.D. The Court allowed Dr. Antonella Tosti, a dermatologist who treats women with hair loss, to testify as to specific causation—i.e., that Taxotere caused the specific bellwether Plaintiffs' PCIA.[233] To reach her opinions, Dr. Tosti relied on another physician to perform biopsies and a pathologist to study the tissue samples.[234] Dr. Tosti

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[227] Rec. Docs. 7807 at 4–5 (*Earnest*); 12109 at 5–6 (*Kahn*).
[228] Rec. Doc. 12109 at 6 (*Kahn*).
[229] Rec. Docs. 7807 at 6 (*Earnest*); 12109 at 7 (*Kahn*).
[230] Dr. Bosserman opined that the writers of the informed consent form, and thus the physicians and patients as well, were not informed about the PCIA risk from Sanofi's clinical trials. Rec. Doc. 12109 at 8 (*Kahn*).
[231] *Id.* at 9.
[232] *Id.*
[233] Rec. Docs. 8095 at 2, 4, 7–9 (Order Denying Defs.' Mot. to Exclude Expert Test. on Specific Causation in *Earnest*); 12401 at 2, 13 (Order Denying Defs.' Mot. to Exclude Test. of Tosti and Defs.' Mot. for Summ. J. on Specific Causation in *Kahn*).
[234] Rec. Docs. 8095 at 4–7 (*Earnest*); 12401 at 5–6 (*Kahn*).

then performed a differential diagnosis using the pathology results, further tests to rule out other causes, her classifications of alopecia, her experience, a review of the medical literature, and the work of the Plaintiffs' other experts.[235] The Court also allowed Dr. Tosti to testify that Ms. Kahn suffered from PCIA attributable to Taxotere rather than the other chemotherapy drugs Ms. Kahn received.[236]

Laura Plunkett, PhD, DABT. Dr. Laura Plunkett, a pharmacologist and toxicologist, was also put forth by the bellwether Plaintiffs to provide expert testimony.[237] In *Earnest*, the parties agreed that Dr. Plunkett would not offer opinions on causation, regulatory activities, Taxotere's efficacy, or Sanofi's promotional activities of Taxotere.[238] Dr. Plunkett was allowed to testify that PCIA differed from drug-induced alopecia ("DIA") in that DIA is not permanent.[239] Dr. Plunkett could also testify that Taxotere was associated with a greater risk of permanent alopecia compared to some other chemotherapy drugs.[240] The Court found her weight-of-the-evidence methodology passed muster.[241]

While the parties agreed that Dr. Plunkett could not provide causation testimony, the Court found that several of Dr. Plunkett's proposed areas of testimony overstepped this limitation. The Court did not permit Dr. Plunkett to testify that Taxotere carried an independent risk of permanent alopecia because she had not conducted a general causation analysis.[242] Further, Dr.

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[235] Rec. Docs. 8095 at 7–10 (*Earnest*); 12401 at 5–11 (*Kahn*).
[236] Rec. Doc. 12401 at 9–13 (*Kahn*).
[237] Rec. Docs. 8097 at 3 (Order Denying in Part & Deferring in Part Defs.' Mot. to Exclude Expert Test. of Plunkett in *Earnest*); 11823 at 1–2 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Expert Test. of Plunkett in *Kahn*).
[238] Rec. Doc. 8097 at 3–4 (*Earnest*).
[239] Rec. Doc. 11823 at 6 (*Kahn*).
[240] Rec. Doc. 8097 at 3–6 (*Earnest*).
[241] Rec. Doc. 11823 at 7–8 (*Kahn*).
[242] *Id.* at 5.

Plunkett could not opine that Taxotere was a "substantial contributing factor" to permanent alopecia because the jury determines proximate causation.[243] Last, the Court did not allow Dr. Plunkett to opine that Taxotere was "more toxic" than Taxol. The Court reasoned that this opinion did not fit the facts of the case, and it could have led the jury to assume, without a sufficient basis, that Taxotere was more likely to cause permanent hair loss.[244]

After Ms. Earnest's trial but before Ms. Kahn's trial, Plaintiffs' regulatory expert Dr. David Kessler left the litigation.[245] Plaintiffs then had Dr. Plunkett submit a supplemental report containing regulatory opinions. Dr. Plunkett opined that Sanofi should have updated the Taxotere label before Ms. Kahn received her treatment in 2008.[246] The Court allowed Dr. Plunkett to offer her regulatory opinion but reiterated that Dr. Plunkett could not offer causation-based opinions.[247] The Court has allowed Sanofi to file additional challenges to the supplemental reports offered by Dr. Plunkett for the renewed *Earnest* trial and her preservation deposition, which will be provided to the relevant courts.

David B. Ross, M.D., PhD, MBI. Ms. Kahn also designated, but did not call, Dr. David Ross as a regulatory expert to replace Dr. Kessler.[248] Dr. Ross worked for FDA as a medical officer from 1996 to 2006.[249] The Court permitted Dr. Ross to provide his FDA regulatory and safety signal opinions based on Dr. Madigan's statistical analysis and the methodology Dr. Ross would use at

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[243] *Id.* at 5–6.
[244] Rec. Docs. 8097 at 6 (*Earnest*); 11823 at 4–5 (*Kahn*).
[245] *See* Rec. Doc. 12173 (Order Denying Defs.' Mot. to Exclude Expert Test. of Kessler as Moot in *Kahn*).
[246] Rec. Doc. 13131 at 2, 4 (Order Granting in Part and Denying in Part Defs.' Mot. to Exclude Suppl. Op. of Plunkett in *Kahn*).
[247] Rec. Doc. 13131 at 5–6 (*Kahn*).
[248] Rec. Doc. 13063 at 1–2 (Order Denying Defs.' Mot. to Exclude Expert Test. of Ross in *Kahn*).
[249] *Id.* at 2.

FDA.[250]

b) Sanofi's Experts

The Court has also assessed the opinions of Sanofi's experts under Rule 702 before both bellwether trials. At both trials, Sanofi called only Dr. John Glaspy to testify as an expert.

Jerry Shapiro, M.D., and Chandra Smart, M.D. Before the *Earnest* bellwether trial, Sanofi designated Dr. Jerry Shapiro, a dermatologist, and Dr. Chandra Smart, a dermatopathologist, to offer opinions on stem cell staining.[251] Stem cell staining was at issue because Plaintiff's general causation expert had opined that PCIA may result due to irreversible damage to stem cells.[252] Further, Plaintiff's dermapathology expert conducted Ki-67 and cytokeratin 15 stem cell staining on Plaintiff's scalp biopsies.[253] The results of the test were positive, evincing that Plaintiff's stem cells were present and proliferating.[254]

The Court agreed with Sanofi that stem cell staining was relevant to disprove Plaintiff's theory that chemotherapy damaged Ms. Earnest's stem cells and caused her persistent alopecia.[255] The Court rejected Plaintiff's argument that Dr. Shapiro and Dr. Smart were not qualified to testify because they were not "stem cell experts."[256] Specifically, the Court noted that Dr. Shapiro had decades of experience as a dermatologist and, in that role, had gained an understanding of stem cell testing.[257] Similarly, the Court found that although Dr. Smart "may not be a 'stem cell expert,' she [was] qualified to read

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[250] *Id.* at 5–6.
[251] Rec. Doc. 8133 (Order Denying Pl.'s Mot. to Exclude Dr. Shapiro's and Dr. Smart's Stem Cell Ops. in *Earnest*).
[252] *Id.* at 5–6.
[253] *Id.* at 6.
[254] *Id.* at 7.
[255] *Id.* at 5–7.
[256] *Id.* at 3.
[257] *Id.* at 4–5.

and understand the results of Plaintiff's stem cell stains."[258] The Court, however, did not permit either expert to refer to the stem cell study conducted for Ms. Earnest as a "failed study" and limited Dr. Shapiro and Dr. Smart to testimony addressing Ms. Earnest's slides only.[259] The Court also explained that it would limit Dr. Shapiro and Dr. Smart's testimony as appropriate if it became unnecessarily cumulative.[260]

In *Kahn*, Sanofi designated only Dr. Shapiro to opine on stem cell staining.[261] The Court reiterated that Dr. Shapiro had sufficient experience with hair disorders to testify on stem cell staining, but again excluded Dr. Shapiro from referring to the stem cell study as a "failed study."[262]

John Glaspy, M.D. Sanofi sought to introduce the testimony of oncologist Dr. John Glaspy to testify on the common types and causes of alopecia he observes and treats in his breast cancer patients.[263] The Court allowed Dr. Glaspy to opine generally on the types and causes of alopecia, as well as on FDA-related topics, including the process of clinical trials, how the "new drug application" process generally operates, and how underlying data from Taxotere clinical trials are submitted to FDA.[264] Based on his experience as an oncologist, Dr. Glaspy was also permitted to opine on the Taxotere label; common sentiments breast cancer patients may have and express about treatment and survival; breast cancer survival rates and how they are affected by various chemotherapy regimens; the alternatives to Taxotere-containing regimens and the absence of any guarantees in the oncological setting; and the

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[258] *Id.* at 5. The Court also noted that an expert is not strictly confined to his or her area of practice but may testify "concerning related applications." *Id.* at 4–5.
[259] *Id.* at 8.
[260] *Id.*
[261] Rec. Doc. 12402 (Order Denying Pl.'s Mot. to Exclude Dr. Shapiro's Ops. in *Kahn*).
[262] *Id.* at 3–5.
[263] Rec. Doc. 11780 at 4–5 (Order Denying Pl.'s Mot to Exclude Test. of John Glaspy, M.D. in *Kahn*).
[264] *Id.* at 4–7.

side effects of chemotherapy drugs, how clinicians weigh side effects, and how and what side effects are communicated to patients.[265]

Before *Earnest*, the Court also permitted Dr. Glaspy to offer causation opinions, relying in part on Dr. Glaspy's review of the Sanofi-sponsored, ten-year multi-center Phase III randomized clinical trial—TAX 316. The Fifth Circuit later reversed and remanded Ms. Earnest's case for a new trial, in part because of Dr. Glaspy's reliance on Dr. Kopreski's testimony on the TAX 316 clinical data without independently reviewing his results. *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Earnest)*, 26 F.3d at 267. During *Kahn*, Dr. Glaspy did not offer any opinions that relied on Dr. Kopreski's testimony about the TAX 316 study.

Janet Arrowsmith, M.D. Dr. Janet Arrowsmith is a doctor in internal medicine, an epidemiologist, and a former FDA employee. In both bellwether cases, the Court permitted Dr. Arrowsmith to testify generally about alternative causes of alopecia, as well as opinions on the following topics: (1) her regulatory opinions, including that reasonable evidence of causal association means a signal is confirmed and "is not merely a 'weak' or 'potential' signal" referred to further evaluation; (2) how "medical and regulatory judgment" is necessary to define a term when statutory definitions are not available; and (3) why she believes permanent alopecia was not appropriate in the "Warning and Precautions" section of the Taxotere label.[266]

In *Kahn*, this Court's denied Plaintiff's request to prohibit Dr. Arrowsmith from testifying about the alleged statistical significance of ongoing alopecia based on the TAX 316 data, including her opinions that relied on the

[265] *Id.* at 6–12.
[266] Rec. Doc. 11781 at 5–8 (Order Denying Pl.'s Mot. to Exclude Test. of Dr. Janet Arrowsmith in *Kahn*).

testimony of Dr. Kopreski.[267] Like Dr. Glaspy's testimony, this portion of her testimony is therefore implicated by the Fifth Circuit's decision *In re Taxotere (Docetaxel) Products Liability Litigation (Earnest)*, 26 F.3d at 267.

L.J. Wei, PhD. Dr. Lee-Jen Wei is a biostatistician and processor of biostatistics.[268] Sanofi designated Dr. Wei to opine on the TAX 316 clinical trial before *Kahn,* including the following opinions: (1) the TAX 316 and TAX 301 studies do not provide evidence of a safety signal of a new or unexpected risk of permanent alopecia compared to alternative chemotherapies; (2) Dr. Madigan's analyses suffer from serious and well-known limitations, rendering them of little or no value in determining whether there is reliable statistical evidence that Taxotere is associated with an increased risk of permanent alopecia; (3) the majority of patients with ongoing alopecia in the TAX 316 study were followed for their alopecia for less than six months, making it impossible to say those patients experienced "irreversible" alopecia; and (4) Dr. Madigan's analyses relating to the Sanofi 2012 Health Canada submission are arbitrary and misleading.[269]

Although Ms. Kahn challenged Dr. Wei's opinions on the TAX 316 clinical trial, the Court found that these opinions were based on sufficient data under Rule 702.[270] Ms. Kahn also challenged Dr. Wei's opinions because Dr. Wei relied on other statisticians from his company, Blue Null, to perform calculations for his report without disclosing this fact in his report.[271] While the Court found the non-disclosure was improper, it reasoned that Dr. Wei's reliance on his colleagues was reasonable under Rule 703, and Ms. Kahn was

[267] *Id.* at 6–7.
[268] Rec. Doc. 12107 (Order Denying Pl.'s Mot. to Exclude Test. of Professor L.J. Wei in *Kahn*).
[269] Rec. Doc. 11103 at 2–3 (Defs.' Opp. to Pl.'s Mot. to Exclude Expert Test. of Dr. L.J. Wei in *Kahn*).
[270] Rec. Doc. 12107 at 4–6 (*Kahn*)
[271] *Id.* at 5–6.

not prejudiced because Dr. Wei disclosed his reliance on others at his deposition.[272]

Gerald Miletello, M.D. Dr. Gerald Miletello is an oncologist with years of experience treating breast cancer and other cancers.[273] In *Kahn*, the Court permitted Dr. Miletello to offer his opinion on alternative causes of alopecia, including chemotherapy drugs other than Taxotere, the aging process, and certain endocrine-based therapies.[274] Dr. Miletello could also offer opinions on the efficacy of taxane-containing regimens; his personal prescribing preferences, including his preference for Taxotere in Ms. Kahn's situation; the risk-benefit analysis he employs in making his prescribing decisions; and his thoughts of the Taxotere label from his perspective as an oncologist.[275] The Court, however, did not permit Dr. Miletello to opine on whether he believed the Taxotere label complied with FDA regulations.[276] Nor could Dr. Miletello offer opinions duplicative of Dr. Glaspy's opinions.[277] The Court also noted that, to the extent Dr. Miletello contradicted his prior testimony about the similar efficacy of Taxotere and Taxol, "Plaintiff [could] illuminate this on cross-examination."[278]

Mamina Turegano, M.D. Sanofi designated Dr. Mamina Turegano as a specific causation expert to testify on the association of various anti-cancer agents and permanent hair loss.[279] The Court found that Dr. Turegano employed a reliable methodology in developing her opinions and permitted Dr.

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[272] *Id.*
[273] Rec. Doc. 11804 at 1 (Order Denying Pl.'s Mot. to Exclude Causation Test. of Dr. Gerald Miltello in *Kahn*).
[274] *Id.* at 4–5.
[275] *Id.* at 5–6.
[276] *Id.* at 6.
[277] *Id.* at 5.
[278] *Id.*
[279] Rec. Doc. 12160 at 3–5 (Order Denying Pl.'s Mot. to Exclude Test. of Dr. Mamina Turegano in *Kahn*).

Turegano to opine on alternative causes of Ms. Kahn's hair loss.[280]

Plaintiff argued that Dr. Turegano did not properly disclose her opinions under Federal Rule of Civil Procedure 26(a)(2)(B) because she did not provide an opinion in her report "as to whether she considered or ruled out Taxotere-containing regimens as a cause of Plaintiff's alleged permanent hair loss."[281] The Court disagreed and found that Dr. Turegano's report compiled with Rule 26, as it provided a complete statement of her opinions, the reasons for them, and the facts and data she considered.[282] The Court noted that "to the extent [Dr. Turegano] failed to spell out the steps of her differential diagnosis," Ms. Kahn could address this during cross examination.[283]

Ellen T. Chang, Sc.D. Dr. Ellen Chang is an epidemiologist specializing in cancer. Before trial, Ms. Kahn moved to exclude Dr. Chang's testimony on (1) the TAX 316 clinical trial, (2) whether other medications can cause PCIA, and (3) the "forms and risk factors" of alopecia.[284] The Court permitted Dr. Chang to testify that persistent alopecia is associated with other medications, as well as to the general "forms and risk factors" of alopecia.[285] But the Court precluded Dr. Chang from testifying that medications that Plaintiff did not take could cause PCIA because they were irrelevant to the case.[286]

Dr. Chang filed a supplemental report in *Kahn*, which offered additional opinions in response to new labeling opinions offered by Dr. Ross and Dr. Plunkett. Ms. Kahn sought to exclude Dr. Chang's opinions as untimely, asserting that Dr. Chang's new opinions should have been included in her

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[280] *Id.* at 5–6.
[281] *Id.* at 5.
[282] *Id.* at 5–6.
[283] *Id.* at 6.
[284] Rec. Doc. 10934 at 1–2 (Pl.'s Mot. to Exclude Certain Ops. of Ellen T. Chang, Sc.D in *Kahn*).
[285] Rec. Doc. 12108 at 4–7 (Order Denying Pl.'s Mot. to Exclude Certain Ops. of Ellen T. Chang, Sc.D in *Kahn*).
[286] *Id.* at 5–6.

original report. The Court, however, found Dr. Chang's supplemental report was "an appropriate rebuttal to the opinions of Dr. Ross and Dr. Plunkett" and allowed Dr. Chang to testify to her supplemental report.[287]

Azael Freites-Martinez, M.D. In *Kahn*, Sanofi sought to introduce the testimony of Dr. Azael Freites-Martinez—a dermatologist who specializes in chemotherapy regimens and persistent alopecia.[288] The Court found that Dr. Freites-Martinez was qualified to testify regarding specific causation and Ms. Kahn's hair loss.[289] The Court noted that Dr. Freites-Martinez "need not be licensed in the United States to opine on Ms. Kahn's hair loss," and that it was "inconsequential" to Dr. Freites-Martinez's specific causation opinion that he did not examine Ms. Kahn in person.[290]

10. Motions in Limine

In advance of the *Earnest* and *Kahn* trials, Sanofi filed 57 motions in limine and Plaintiffs filed 38. While most are necessarily influenced by case-specific facts and jurisdiction-specific law, the Court nevertheless provides a listing of these motions in appended Exhibit A which reflects the motions in limine for both trials, and indication of the filing party, and the rulings, for the benefit of the remand courts should they find such rulings instructive.

II. NATURE AND EXPECTED DURATION OF FURTHER PROCEEDINGS

Because all general fact and expert discovery has been completed in the MDL, the courts receiving these cases need not be concerned with facilitating general expert, corporate, and third-party discovery. Case-specific discovery

[287] Rec. Doc. 13072 at 4–6 (Order Denying Pl.'s Mot. to Strike the Untimely Report of Ellen Chang, ScD in *Kahn*).
[288] Rec. Doc. 12404 (Order Denying Pl.'s Mot. to Exclude Test. of Azael Freites-Martinez in *Kahn*).
[289] *Id.* at 4–8.
[290] *Id.* at 6–7.

and trial preparation, however, will be determined on remand or transfer. As noted in the Wave Work Up section of this Order, the Wave 1 Plaintiffs have undergone limited case work-up. Specifically, the parties have conducted records collection and completed depositions of Plaintiff. Some parties have also completed depositions of Plaintiff's prescribing physician, a sales representative, and, where applicable, a treating physician. Receiving courts can anticipate additional case-specific fact discovery, including Plaintiff's spouse, if any, friends and family, and healthcare providers. In addition, this Court did not enter any inventory-wide medical diagnosis order. As a result, case-specific expert discovery likely will require dermatology experts to corroborate each Plaintiff's claim that she experienced PCIA caused by Taxotere. In each of the trial cases, this has entailed the taking of scalp biopsies and certain sharing provisions for reading such pathology by each side's experts.

Receiving courts should also expect to address case-specific motions for summary judgment on dispositive issues, such as the statute of limitations and warnings causation. Additional motion practice will likely include case-specific expert challenges under Federal Rule of Evidence 702. Before trial, receiving courts may also anticipate ruling on case-specific motions in limine and objections to case-specific deposition designations and exhibits.

III. COMMON BENEFIT WORK

Attorneys in this MDL—in particular, the PEC, PSC, Plaintiffs' Settlement Committee, and certain subcommittee contributing counsel—have expended significant resources and made substantial common-benefit contributions to this MDL on behalf of all Plaintiffs.[291] All counsel on the PSC

[291] *See* Pretrial Orders Nos. 2, 6, 8, 19, 20, 31, 75, 89, 93 (Docs. 104, 133, 156, 262, 265, 305, 1507, 5377, 6018).

or authorized by the PSC to do common benefit work are skilled, experienced and capable professionals. Therefore, these attorneys should be entitled to the fair and equitable assessment of any recovery for the services performed and expenses incurred by attorneys acting for MDL administration and common benefit of all plaintiffs in this complex litigation.[292]

"The effect of an order remanding a case to the transferor court for trial is to divest the transferee court of jurisdiction in the case and to vest the transferor court with jurisdiction."[293] "The Panel's power to sever and remand a portion of an action is limited to entire claims. The Panel cannot remand only part of a claim or only certain factual issues."[294] The award of attorney's fees, nevertheless, is a "collateral matter over which a court normally retains jurisdiction even after being divested of jurisdiction on the merits."[295]

Accordingly, because the fees awarded to the MDL attorneys for the common benefit of all Plaintiffs is a collateral issue separate from the merits of this case, the Court suggests that it retains jurisdiction to consider the fair and equitable assessment of any potential recovery for the services performed and expenses incurred by attorneys acting for administration and common benefit of all MDL plaintiffs.

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[292] *See* Pretrial Order 19 (Doc. 262); Order and Reasons of November 15, 2022 modifying the common benefit holdback percentages for fees (to 15%) and expenses (to 4.75%) of any recovery (Doc. 15143); *In re* FedEx Ground Package Sys., Inc. Employment Practices Litig., No. 3:05-MD-527 RM, 2010 WL 785279, at *5–6 (N.D. Ind. Mar. 2, 2010).

[293] *Id.* (citing David F. Herr, Multidistrict Litigation Manual, § 10:5 (2005)).

[294] *Id.* (citation omitted).

[295] *Id. See also In re* Zyprexa Prods. Liab. Litig., 467 F. Supp. 2d 256, 274 (E.D.N.Y. 2006) (citations omitted); In re Zyprexa Prods. Liab. Litig., 594 F.3d 113, 2010 WL 367556, *10 (2d Cir. 2010) (stating that order imposing an assessment to create a fund that could be used to compensate attorneys who demonstrate that their efforts conferred a benefit on the Plaintiffs generally is "even less related to the ultimate merits than orders awarding attorney's fees, which are collateral matters over which a court retains jurisdiction even if it ultimately is determined to lack subject matter jurisdiction.").

New Orleans, Louisiana, this 11th day of May, 2023.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

EXHIBIT A

REC. DOC.	TOPIC	FILED BY	RULING
7643	Sanofi's Corporate Character and Good Acts	Plaintiff	Deferred due to vagueness (Rec. Doc. 8206)
7644	Plaintiff's Experts Have Not Publicized/Published or Submitted Their Opinions to the FDA or Any Other Organizations	Plaintiff	Denied (Rec. Doc. 8206)
7645	"Stem Cell" Staining	Plaintiff	Dismissed as moot (Rec. Doc. 8206)
7646	Plaintiff Counsel Advertisements	Plaintiff	Granted in part, denied in part (Rec. Doc. 8206)
7647	Unrelated Medical Conditions, Familial Medical History of Cancer, and Unrelated Medication Usage	Plaintiff	Granted in part, denied in part (Rec. Doc. 8201)
7648	Discussing Certain Matters in the Presence of the Jury or Potential Jurors	Plaintiff	Granted in part, denied in part (Rec. Doc. 8206)
7649	Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy	Plaintiff	Granted in part, denied in part (Rec. Doc. 8201)
7650	Healthcare Costs and Insurance as a Collateral Source	Plaintiff	Granted in part, denied in part (Rec. Doc. 8206)
7651	Other Chemotherapy Medications or Medical Conditions That Purportedly Cause Permanent Hair Loss	Plaintiff	Granted in part, denied in part (Rec. Doc. 8198)
7652	Instances of Permanent Alopecia Among Those Prescribed Taxotere by Sanofi's Experts	Plaintiff	Granted (Rec. Doc. 8198)
7653	Dr. Carinder is Responsible for Plaintiff's Condition	Plaintiff	Granted in part, denied in part (Rec. Doc. 8198
7657	What Treatment Dr. Carinder Would Prescribe to Plaintiff Today	Defendant	Granted (Rec. Doc. 8206)

REC. DOC.	TOPIC	FILED BY	RULING
7657	What Plaintiff Would Have Done Differently if She had been Given Different Risk Information by Her Prescribing Oncologist	Defendant	Denied (Rec. Doc. 8206)
7657	Sanofi Promotional and/or Marketing Materials Not Possessed or Relied On by Plaintiff or Her Prescribing Physician	Defendant	Denied (Rec. Doc. 8201)
7657	Non-Expert Causation Testimony	Defendant	Deferred (Rec. Doc. 8206)
7657	Plaintiff's Motive and/or Mental State	Defendant	Granted in part, deferred in part (Rec. Doc. 8206)
7657	Sanofi Sales Representative	Defendant	Denied (Rec. Doc. 8201)
7658	Correspondence Between DDMAC and Sanofi	Defendant	Granted (Rec. Doc. 8201)
7659	FDA Approval	Plaintiff	Granted in part, denied in part, deferred in part (Rec. Doc. 8201)
7660	Taxotere Has Saved Lives	Plaintiff	Granted in part, denied in part (Rec. Doc. 8198)
7661	Other Individuals' Personal Use of Taxotere and Personal Experience With Cancer	Plaintiff	Deferred (Rec. Doc. 8206)
7662	Sanofi as a "French" or "Foreign" Company	Defendant	Granted in part, denied in part (Rec. Doc. 8206)
7664	Alleged "High Toxicity" of Taxotere Causes or Is Associated With Alopecia	Defendant	Dismissed as moot (Rec. Doc. 8206)
7666	Foreign Labeling and Regulatory Actions	Defendant	Granted in part, denied in part (Rec. Doc. 8201)
7668	"Ongoing Alopecia" Data Observed in the Tax316 and GEICAM 9805 Clinical Trials Represents Evidence of "Persistent," "Permanent," or "Irreversible" Alopecia	Defendant	Denied (9/5/2019 Hearing Transcript, 110:23-111:3)
7670	Shirley Ledlie and Any "Taxotears" or Other Third Party Advocacy or Communications Group or Group Members	Defendant	Granted (Rec. Doc. 8201)

REC. DOC.	TOPIC	FILED BY	RULING
7671	Company Conduct That Post-Dates Plaintiff's Chemotherapy Treatment	Defendant	Granted (Rec. Doc. 8201)
7673	FDA's January 2011 Warning Letter and Corresponding 483 Inspection	Defendant	Granted (Rec. Doc. 8216)
7720	Purported Moral Or Ethical Duties of Pharmaceutical Drug Manufacturers	Defendant	Granted (Rec. Doc. 8206)
7720	Purported Legal Duties and Conclusions	Defendant	Deferred (Rec. Doc. 8206)
7720	Other Lawsuits, Claims, or Investigations Against Defendants and/or Other Sanofi Entities	Defendant	Granted in part, denied in part (Rec. Doc. 8206)
7720	Complaints and Lawsuits Against Other Manufacturers of Docetaxel	Defendant	Granted in part (Rec. Doc. 8206)
7720	Adverse Event Reports or Other Complaints Involving Patients Other Than Plaintiff	Defendant	Deferred (Rec. Doc. 8216)
7720	Presence, Absence, or Identity of Defendants' Corporate Representative at Trial	Defendant	Granted (Rec. Doc. 8206)
7720	Defendants' Executive and/or Employee Compensation	Defendant	Deferred (Rec. Doc. 8206)
7720	Cost of Taxotere or Prescription Drug Pricing Generally	Defendant	Granted (Rec. Doc. 8206)
7720	Defendants' Corporate Finances or Employment Decisions	Defendant	Deferred (Rec. Doc. 8206)
7720	Expert Opinions That Exceed the Scope of Plaintiff's Experts' Rule 26 Expert Disclosures	Defendant	Deferred (Rec. Doc. 8206)
7720	Defendants' Corporate Intent, Motives, or State of Mind	Defendant	Granted in part, denied in part (Rec. Doc. 8206)
7720	Defendants' Corporate Integrity Agreements, Government Investigations or Settlements, and Any Other Alleged "Bad Acts" Unrelated to Taxotere	Defendant	Granted (Rec. Doc. 8206)
7720	Specific Litigation Conduct	Defendant	Granted (Rec. Doc. 8206)
7720	Alleged Fraud on the FDA	Defendant	Deferred (Rec. Doc. 8206)

REC. DOC.	TOPIC	FILED BY	RULING
12888	Healthcare Costs and Insurance as a Collateral Source	Plaintiff	Granted in part, denied in part (Rec. Doc. 13260)
12889	"Stem Cell" Staining	Plaintiff	Granted in part, denied in part (Rec. Doc. 13260)
12890	Taxotere Has Saved Lives	Plaintiff	Granted in part, denied in part (Rec. Doc. 13260)
12891	Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy	Plaintiff	Granted in part, denied in part (Rec. Doc. 13260)
12892	Sanofi's Corporate Character and Good Acts	Plaintiff	Granted in part, deferred in part (Rec. Doc. 13260)
12893	Defense Counsel Commenting on or Discussing Certain Matters in the Presence of the Jury or Potential Jurors	Plaintiff	Granted in part, denied in part (Rec. Doc. 13260)
12894	American Cancer Society Breast Cancer Dictionary	Plaintiff	Deferred (Rec. Doc. 13260)
12895	Low Quality Photographs	Plaintiff	Deferred (Rec. Doc. 13260)
12896	Prejudicial Litigation Conduct	Plaintiff	Deferred (Rec. Doc. 13260)
12897	Plaintiff's Counsel's Advertisements	Plaintiff	Granted in part, denied in part (Rec. Doc. 13260)
12898	Personal Use of Taxotere or Other Cancer Drugs by Any Defendant Employee Witness, Expert Witness, Attorney, and/or Family Member, or Their Personal Experiences With Cancer	Plaintiff	Deferred (Rec. Doc. 13260)
12899	Taxotere Has Been Proven Superior to Taxol – Or Any Drug Other Than 5-FU – Or That Taxotere Gave Plaintiff the "Best Chance" of Surviving Cancer, Or That Taxotere Gave Her the "Best Chance" for Preventing Her Cancer From Returning	Plaintiff	Granted in part, denied in part (Rec. Doc. 13260)
12900	Instances of Permanent Alopecia Among Those Prescribed Taxotere by Sanofi's Experts	Plaintiff	Granted (Rec. Doc. 13260)

REC. DOC.	TOPIC	FILED BY	RULING
12901	Unrelated Medical Conditions, Unrelated Familial Medical History, and Unrelated Medication Usage	Plaintiff	Granted in part, denied in part, deferred in part (Rec. Doc. 13260)
12902	Improper Arguments or Suggestions Regarding FDA Approval	Plaintiff	Conditionally granted (Rec. Doc. 13260)
12903	Unsupported Statements From Counsel in Opening and Closing Statements	Plaintiff	Granted (Rec. Doc. 13260)
12905	Comparative Fault of her Treating Physicians and Misuse of Taxotere	Plaintiff	Granted in part, denied in part (Rec. Doc. 13260)
12907	Online Advocacy	Plaintiff	Denied (Rec. Doc. 13260)
12909	Use of Unreliable Evidence to Support Claims of Alternative Causation and/or Questioning Which Misconstrues the Applicable Burden	Plaintiff	Denied (Rec. Doc. 13260)
12968	Purported Moral or Ethical Duties of Pharmaceutical Drug Manufacturers	Defendant	Granted (Rec. Doc. 13260)
12968	Purported Legal Duties and Conclusions	Defendant	Deferred (Rec. Doc. 13260)
12968	Other Lawsuits, Claims, or Investigations Against Defendants and/or Other Sanofi Entities	Defendant	Granted in part, denied in part (Rec. Doc. 13260)
12968	Complaints and Lawsuits Against Other Manufacturers of Docetaxel	Defendant	Granted in part (Rec. Doc. 13260)
12968	Adverse Event Reports or Other Complaints Involving Patients Other Than Plaintiff	Defendant	Deferred (Rec. Doc. 13260)
12968	Presence, Absence, or Identity of Defendants' Corporate Representative at Trial	Defendant	Granted (Rec. Doc. 13260)
12968	Defendants' Executive and/or Employee Compensation	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Cost of Taxotere and Prescription Drug Pricing Generally	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Defendants' Corporate Finances or Employment Decisions	Defendant	Conditionally granted (Rec. Doc. 13260)

REC. DOC.	TOPIC	FILED BY	RULING
12968	Expert Opinions that Have Been Disclaimed and/or that Exceed the Scope of Plaintiff's Experts' Rule 26 Disclosures and Deposition Testimony	Defendant	Denied (Rec. Doc. 13260)
12968	Defendants' Corporate Intent, Motives, or State Of Mind	Defendant	Granted in part, denied in part (Rec. Doc. 13260)
12968	Defendants' Corporate Integrity Agreements, Government Investigations or Settlements, or Any Other Alleged "Bad Acts" Unrelated to Taxotere	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Specific Litigation Conduct	Defendant	Granted (Rec. Doc. 13260)
12968	Alleged Fraud on the FDA	Defendant	Deferred (Rec. Doc. 13260)
12968	Reference to PCIA as "Common"	Defendant	Denied (Rec. Doc. 13260)
12968	What Ms. Kahn Would Have Done Differently if She Had Been Given Different Risk Information by Her Prescribing Oncologist	Defendant	Deferred (Rec. Doc. 13260)
12968	Sanofi Promotional and/or Marketing Materials Not Possessed or Relied On by Ms. Kahn or Her Prescribing Physician	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Non-Expert Causation Testimony	Defendant	Deferred (Rec. Doc. 13260)
12968	Plaintiff's Motive and/or Mental State	Defendant	Granted in part, deferred in part (Rec. Doc. 13260)
12968	Sanofi Sales Representatives, and to Exclude Sales Representative Witness Testimony	Defendant	Denied (Rec. Doc. 13260)
12968	Correspondence Between DDMAC and Sanofi	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Referring to Sanofi as a "French" or "Foreign" Company	Defendant	Granted in part, denied in part (Rec. Doc. 13260)
12968	FAERS Signal Evaluation	Defendant	Denied (Rec. Doc. 13260)
12968	Foreign Labeling and Regulatory Actions	Defendant	Granted in part, denied in part (Rec. Doc. 13260)

REC. DOC.	TOPIC	FILED BY	RULING
12968	"Ongoing Alopecia" Data Observed in the TAX316 and GEICAM 9805 Clinical Trials Represents Evidence of "Persistent," "Permanent," or "Irreversible" Alopecia	Defendant	Denied (Rec. Doc. 13260)
12968	Shirley Ledlie, any "Taxotears" or Other Third Party Advocacy or Communications Group or Group Members, Facebook Voices Page, And Intouch Solutions	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Company Conduct that Post-Dates Plaintiff's Chemotherapy Treatment	Defendant	Granted in part, deferred in part (Rec. Doc. 13260)
12968	FDA's January 2011 Warning Letter and Corresponding 483 Inspection	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Plaintiff's Actinic Keratosis was Caused By Taxotere or PCIA, or Claiming Damages Therefor	Defendant	Granted in part, denied in part (Rec. Doc. 13260)
12968	Use of Cold Caps	Defendant	Granted (Rec. Doc. 13260)
12968	Canadian Informed Consent	Defendant	Denied (Rec. Doc. 13260)
12968	Dr. Kessler or his Role in the U.S. Government's Covid-19 Response Team	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Duplicative Expert Testimony	Defendant	Granted (Rec. Doc. 13260)
12968	Punitive Damages Evidence	Defendant	Conditionally granted (Rec. Doc. 13260)
12968	Dear Health Care Provider Letters	Defendant	Denied (Rec. Doc. 13260)
13422	Alternative Causation	Plaintiff	Denied (Rec. Doc. 13433)